

Attorney Docket No: 10123/00301 (03-008)

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REMARKSI. INTRODUCTION

Claims 1-19 and 23-26 are pending in the present application. In view of the following remarks, it is respectfully submitted that all of the pending claims are allowable.

II. CLAIM REJECTIONS - 35 U.S.C. § 102(a)

Claims 1-4, 12-14 and 26 stand rejected under 35 U.S.C. § 102(a) as anticipated by U.S. Patent 3,788,327 to Donowitz et al. ("Donowitz"). (See 1/25/07 Office Action, p. 2.)

Claim 1 recites "[a] valve apparatus for medical applications, comprising a *first flexible disk extending across a first lumen through which a flow of materials is to be controlled, the first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit extending through the first flexible disk*, the first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk and, when a pressure at least as great as the threshold value is applied to the first flexible disk, the first moveable elements are moved to an open position separated from one another along the at least one first slit permitting flow through the first lumen."

In contrast, Donowitz describes a double-reed valve 48 that includes no flexible disk extending across a lumen to control fluid flow therethrough. The valve 48 is disposed within a generally cylindrical body member 28 containing an axial fluid passageway 30 extending from an inlet end 38 to an outlet end 40. The body member 28 progressively widens from the inlet end 38 to the outlet end 40. The valve 48 comprises "a pair of opposing flexible

Attorney Docket No: 10123/00301 (03-008)

web or reed-like members” 50, 52, which are normally urged to a closed position. (Donowitz, col. 3, ll. 3-9.) When the pressure exerted on the bottom surfaces 54, 56 of reed members 50, 52 increases by a predetermined amount relative to the pressure exerted on the top surfaces 58, 60 of reed members 50, 52, the reed members 50, 52 deflect upward (i.e. the valve opens to allow fluid flow through the lumen). (See *id.*, col. 3, ll. 11-18.)

Claim 1 recites a “*first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit*” which is structurally different from the double-reed valve 48 of Donowitz. Citing Webster’s Online Dictionary, the Examiner asserts that the word “disk” refers to a “thin circular object.” However, even using this definition, the valve 48 of Donowitz should not be considered a disk. The reed members 50 and 52, rather, are two separate structures. While reed members 50, 52 do meet to prevent fluid flow along passageway 30 under certain conditions, they are not structurally joined and do not comprise a single disk. As shown most clearly in Fig. 3 of Donowitz, the opening (not numbered) separating the reed members 50 and 52 extends the entire diameter of the passageway 30, further demonstrating that the reed members 50 and 52 are two separate objects rather than components of a disk. Additionally, Donowitz always refers to the reed members 50, 52 as two separate objects. (See *id.*, col. 3, ll. 5, 12, 14, 42, 51.) No suggestion is made that reed members 50, 52 may comprise a single disk; reed members 50, 52 are consistently described by Donowitz as two separate structural entities.

Furthermore, it is respectfully submitted that the double-reed design of the valve 48 of Donowitz is critical to its function -- i.e., this shape enables the valve 48 to limit flow therethrough to a single direction. Due to the double-reed design of the valve 48, when the pressure differential is the opposite of the above (i.e. when pressure is increased on upper surfaces 58, 60 relative to that on lower surfaces 54, 56), the valve 48 remains closed, rather than opening to permit flow in the opposite direction. (See *id.*, col. 4, ll. 46-51.) That is, fluid pressure in the opposite direction operates on the reeds 50, 52, forcing them toward each other to

Attorney Docket No: 10123/00301 (03-008)

add to the biasing force urging the reeds 50, 52 to seal the valve 48. There is no showing or suggestion in Donowitz to modify this shape and there is clearly no showing or suggestion, nor any motivation, to substitute a flexible disk for this double reed valve.

Because claims 2-4 and 12-14 depend from, and, therefore, include all of the limitations of claim 1, it is respectfully submitted that these claims are also allowable for the reasons stated above.

Claim 26 recites a flow shutoff device comprising "a housing attachable to a patient line" and "a pressure actuated valve mounted within the housing to selectively restrict flow therethrough, the valve comprising *a flexible disk including a plurality of movable elements separated by a slit extending through the disk*, the movable elements being biased toward a closed position and being movable to an open position when a pressure applied to the valve exceeds a predetermined threshold value, wherein flow through the housing is prevented when the movable elements are in the closed position."

For the same reasons as described above in regard to claim 1, it is respectfully submitted that Donowitz neither discloses nor suggests "*a flexible disk including a plurality of movable elements separated by a slit extending through the disk*," as recited in claim 26.

### III. CLAIM REJECTIONS - 35 U.S.C. § 103(a)

Claims 5-7, 9-11, 15-17, and 23-25 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Donowitz in view of U.S. Patent 5,810,789 to Powers et al. ("Powers"). (See 1/25/07 Office Action, p. 3.) The Examiner stated that Donowitz discloses a valve apparatus that includes all of the limitations as recited in claim 1, but does not describe the addition of a housing attached to a dual lumen catheter with a valve apparatus in each lumen to regulate fluid flow. (See *id.*) To cure this deficiency, the Examiner cites Powers. However, it is respectfully

Attorney Docket No: 10123/00301 (03-008)

submitted that Powers does not cure the deficiencies described above in regard to the anticipation rejections of the independent claims. Powers does not disclose or suggest a valve in the form of a *“first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit”* as recited in claims 1 and 15, from which these claims depend. Moreover, as stated above, any modification that would alter the double-reed valve of Donowitz, without specifically providing for the maintenance of one way flow, is taught away from by Donowitz.

In addition, it is respectfully submitted that Powers does not disclose or suggest a valve with a slit having *“first moveable members being biased so that, when a pressure less than a predetermined threshold value is applied to the first flexible disk, the first moveable elements are maintained in a closed position in which no flow is permitted past the first flexible disk,”* as recited in claims 1 and 15.

Because claims 5-7, 9-11, 16-17 and 23-25 depend from, and, therefore, include all of the limitations of, claims 1 and 15, it is respectfully submitted that these claims are not rendered obvious by Donowitz in view of Powers, and that this rejection should be withdrawn.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Donowitz in view of U.S. Patent 6,099,505 to Ryan et al. (“Ryan”). (*See* 1/25/07 Office Action, p. 4.) The Examiner stated that Donowitz discloses a device that includes all of the limitations as recited in claim 3, but does not disclose another pair of slits intersecting at the end of the first slit. (*See id.*) The Examiner cites Ryan to cure this deficiency. However, it is respectfully submitted that Ryan does not cure the deficiencies pointed out in regard to the anticipation rejection of independent claim 1, from which claim 3 depends. Specifically, Ryan does not show or suggest a *“first flexible disk including a plurality of first movable elements formed on opposite sides of at least one first slit,”* as recited in claim 1.

Furthermore, claim 8 recites a “valve apparatus according to claim 3, wherein the

Attorney Docket No: 10123/00301 (03-008)

first flexible disk further includes *a pair of second slits, each of the second slits intersecting a corresponding end of the first slit.*" (See Fig. 6) In contrast, Ryan discloses a surgical trocar assembly including a disposable valve assembly with a tricuspid valve. A tricuspid valve is typically constructed with three slits converging at the center of the disk. (See Ryan, col. 7, ll. 50-53.) A tricuspid valve has only one set of second slits at one end of the first slit. (See Ryan, Fig. 2f.) Therefore, it is respectfully submitted that the valve apparatus of Ryan does not comprise "*a pair of second slits, each of the second slits intersecting a corresponding end of the first slit,*" as recited in claim 8.

It is therefore respectfully submitted that claim 8 is not rendered obvious by Donowitz in view of Ryan, and that this rejection should be withdrawn.

Claims 18 and 19 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Donowitz and Powers as applied to claim 15 above, and in further view of Ryan. The Examiner states that Donowitz and Powers describe a device that discloses all of the limitations as recited in claim 15, but do not disclose another pair of slits intersecting at the end of the first slit. (See 1/25/07 Office Action, p. 4.) To cure this deficiency the Examiner cites Ryan. However, it is respectfully submitted that Ryan does not cure the deficiencies left by Donowitz and Powers, as described above, in regard to independent claim 15.

Because claims 18 and 19 depend from, and, therefore, include all of the limitations of, claim 15, it is therefore respectfully submitted that these claims are not rendered obvious by Donowitz and Powers in further view of Ryan, and that this rejection should be withdrawn.

Attorney Docket No: 10123/00301 (03-008)

**CONCLUSION**

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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